DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2000

Mr. Mel Longhurst
Regulatory Affairs Director
Corin Spinal Systems Limited
The Corinium Centre,
Circencester, Gloucestershire
GL7 IYJ
United Kingdom

Re: K000634
Trade Name: Rod-to-Rod Spinal Cross Brace to be used with the Corin Spinal System
Regulatory Class: II
Product Code: KWQ, KWP and MNH
Dated: February 24, 2000
Received: February 25, 2000

Dear Mr. Longhurst:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000634

Indications for use

The indications for use in respect of the Corin Spinal System are as follows:

The Mehdian Lumbo-Sacral Pedicle Screw indications for use are as follows:

1. The device system consisting of screws, washers, spacers, utilising the anterolateral/anterior surgical approach is intended for the following uses:

   (a) anterolateral screw fixation to the non-cervical spine,
   (b) anterior screw fixation to the cervical spine

   The anterolateral/anterior system is intended for use in the following indications:

   (a) Degenerative disc disease of the lumbar thoracic and cervical spine relating to discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies.
   (b) Spondylolisthesis
   (c) Trauma
   (d) Spinal Stenosis
   (e) Scoliosis
   (f) Kyphosis
   (g) Tumour
   (h) Pseudoarthrosis
   (i) Revision of previous surgery
   (j) Neoplastia

2. The device system consisting of hooks, screws, washers, spacers, when utilised as a non-pedicle posterior system has the following intended use:

   (a) Hook and sacral/iliac screw fixation to the non-cervical spine.

   The non-pedicle posterior devices may be used for the following indications.
   (a) Degenerative disc disease of the lumbar thoracic and cervical spine relating to discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies
   (b) Spondylolisthesis
   (c) Trauma
   (d) Spinal Stenosis
   (e) Scoliosis
   (f) Kyphosis
   (g) Tumour
   (h) Pseudoarthrosis
   (i) Revision of previous surgery
   (j) Neoplastia

NRO for JZP

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Division of General Restorative Devices
510(k) Number K000634

Prescription Use YES
(Per 21 CFR 801.109)

3. The device system consisting of hooks, spacers, sacral/iliac screws, and pedicle screws is intended for patients:

(a) Having a severe spondylolisthesis (grades 3 and 4) at the L5-S1 joint
(b) Who are receiving fusions using autogenous bone graft only
(c) Who are having the device fixed or attached to the lumbar and sacral spine
(d) Who are having the device removed after the development of a solid fusion mass

The levels of pedicle screws fixation will be L3-S1.

MRD for JZD

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Prescription Use Yes
(Per 21 CFR 801.109)

~~TOTAL P.01~~